

CB-1611

Evidence-based laboratory test order sets in first line care

Introduction

The aim of the KCE Trials programme is to ensure that high quality research information is produced on the effectiveness, costs and broader impact of health technology in the most efficient way for those who use, manage, provide care in or develop policy for the Belgian healthcare system.

An overview of the selection procedure can be found in the document "Information for candidate sponsors and guidance note for expression of interest" (v1.1), associated with this commissioning brief and available on our website.

Research question

Is the use of evidence-based order sets for laboratory tests, implemented within a computerised physician order entry (CPOE) system, (cost)effective?

- 1. Intervention:** Evidence-based order sets for laboratory tests based on indication, implemented within a COPE system. The proposed study should focus on specific indications, to be defined by the applicant.
- 2. Patient group:** patients for whom laboratory tests would be ordered, to be defined by the applicant.
- 3. Setting:** general practitioners using a CPOE system.
- 4. Control:** CPOE without evidence-based laboratory test order sets.
- 5. Study design:** cluster-randomised trial with randomisation on the level of physician or practice, to be defined by applicant; with or without internal pilot to test the ability to recruit and randomise physicians. If a pilot is included, the criteria to continue or not from pilot to full trial should be specified.
- 6. Important outcomes:** to be defined by the applicant. Outcomes should not only include process outcomes (e.g. appropriateness, test volume) but also clinical and health economic outcomes. The use of linked billing data can be considered.
- 7. Minimum duration of follow-up:** 1 year

Decision problem to be addressed by this research:

Thirty percent of patient contacts in primary care result in the ordering of laboratory tests. Research shows that many of these orders are inappropriate. Inappropriate laboratory testing can cause harm, stress for patients, and lead to medical errors. Over ordering of laboratory tests leads to unnecessary tests, false positives and unwarranted additional interventions. Under ordering of laboratory tests can result in missed or delayed diagnoses.

Decision support systems such as order sets have been shown to reduce the number of tests ordered and may improve compliance to evidence-based guidelines.

Sound research is required to measure the effects of decision support systems on the appropriateness of laboratory test ordering, taking into account relevant patient outcomes and downstream consequences.

KCE TRIALS PROGRAMME

Notes to Applicants

To ensure the highest quality research, the appropriate guidelines and regulations must be followed and KCE recommendations for applicants are provided.

Methodology: for many of the research questions posed by the KCE Trials programme, a randomised controlled trial is the most appropriate method of providing an answer. Suggestions for how a randomised controlled trial could be designed and constructed most efficiently are encouraged.

Quality, ethical and legal: applicants are asked to follow the Declaration of Helsinki and ICH-GCP guidelines and all applicable legislation such as Belgian Law of 7 May 2004 concerning experiments on the human person, when planning their trial. Note that trials involving medicinal products must comply with "The Medicines for Human Use (Clinical Trials) Regulations 2004" and be submitted to the Federal Agency for Medicines and Health Products (FAMHP). The [FAMHP website](#) contains the latest information about Clinical Trial regulations.

Inspections by FAMHP to document conformity with GCP requirements and local legislation can take place at any time during the progress of KCE funded studies.

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety and made available to the general public.

Clinical Trials Toolkit

General information on the conduct of clinical trials can be found in the [Clinical Trials Toolkit](#). This NIHR resource is designed to help researchers navigate through the complex landscape of setting up and managing clinical trials. Please note that the website is developed for the UK, therefore local regulations and references may not apply in Belgium.

Research networks

The KCE Trials programme expects, where appropriate, that applicants will work with relevant existing research networks.

Making an application

If you wish to submit an Expression of Interest (EOI) on this topic, complete the associated application form available on our website, and submit it (as a PDF) via email to trials@kce.fgov.be by **August 8th before 13.00 hours**. Applications received after 13.00 hours on the due date will not be considered.

Applications will be considered by the KCE Trials Board at its meeting on September 7th.

Please read the document "Information for candidate sponsors and guidance note for expression of interest", associated with this commissioning brief and available on our website.

IMPORTANT: For shortlisted EOI, investigators will be given six weeks to submit a full research proposal.